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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/663,777	09/17/2003	Ricardo Gamboa		2957

7590 08/08/2007  
RICARDO GAMBOA  
Calle 8 No 823 Entre 523 Bis Y 524  
TOLOSA, 1900  
ARGENTINA

EXAMINER
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ISABELLA, DAVID J

ART UNIT	PAPER NUMBER
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3738

MAIL DATE	DELIVERY MODE
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08/08/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

Application No.

10/663,777

Applicant(s)

GAMBOA, RICARDO

Examiner

DAVID J. ISABELLA

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 30 May 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-7 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-7 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 30 May 2007 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

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Receipt is acknowledged of a request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e) and a submission, filed on 5/30/2007. The submission is fully responsive to the prior Office action and has been entered.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-7 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 as worded is indefinite, as there are some languages that obfuscate the meaning of the claim. For examples only:

Recitation of "second upper section both centered on and extending a common warped axis , the first section being a tubular mesh covered at least in some parts by an impermeable polymer with a curvature between 35-45° and having" is unclear as to its meaning. The recitation would be better worded as -- both centered on and extending along a common warped axis having a radius of curvature between 35-45 degrees, the first section being a tubular mesh covered at least in part by an impermeable polymer--.

Recitation of "branches one of which is longer than the other, extends along the warped axis, and is of substantially circular and uniform cross- sectional shape, the

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other branch being formed with a short" would be better worded as --longer than the other, the longer branch extends along the warped axis--.

Recitation of "with a diameter between 10-13 mm, the branches forming with the conduit a distorted "Y" each branch having a mesh of thread partially covered by an impermeable polymeric material and being" would be better worded as --forming with the first lower portion a distorted "Y", each brand having a mesh at least in part covered with an impermeable polymeric material--.

Recitation of "the short branch having a wall that intercepts between 50%-70% of blood flowing up through the tubular conduit from its lower end, the lower end being constructed for connection with a lower vena cava and a hepatic vena with the upper and lower sections of the tubular conduit lodged inside the right atrium, one branch being tightly lodged inside a left pulmonary artery and forming an obstruction with regard to a main pulmonary artery, the other branch being lodged at a base of a right pulmonary artery" would be better worded as --with the upper and lower sections of the tubular conduit configured to be lodged inside the right atrium, one branch sized to be tightly lodged inside a left pulmonary artery ...the other branch configured to be lodged at a base of a right pulmonary artery--.

Claim 3 is indefinite. The claim should be reworded as follows:

The fenestrated asymmetric intracardiac device according to claim 1, characterized in that wherein the first lower section [1,] has a mesh part that is independent of the second upper section and the first section is axially deployable

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within the second section, whereby the first section can be telescoped to variable length.

Claim 5 is indefinite. The claim should be reworded as follows:

The fenestrated asymmetric intracardiac device according to claim 1, characterized in that wherein the mesh structure of the lower end of the first section is free of the impermeable polymeric material rendering it permeable to blood flow from a lower vena cava and hepatic vena.

Claim 7 is indefinite. The claim should be reworded as follows:

The fenestrated asymmetric intracardiac device according to claim 1, characterized in that wherein the mesh is linked metallic threads forming an elastically deformable conduit and wherein the impermeable polymeric material is polytetrafluoroethylene.

### ***Allowable Subject Matter***

Claims 1-7 would be allowable if rewritten or amended to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action.

The following is a statement of reasons for the indication of allowable subject matter: the prior art fails to disclose and/or teach in combination, an asymmetric intracardiac device for total cavopulmonary anastomosis wherein the device comprises a bifurcated tubular conduit formed by a first lower section and a second upper section

both centered on and extending along a common warped axis having a radius of curvature between 35-45°.

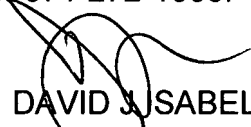
The conduit having a lower end of substantially circular cross-sectional shape with a diameter between 16-20 mm and an upper end having a progressively flattened and a substantially oval cross-sectional shape, the second upper section having a cross-sectional shape that is oval and tapers upward to a diameter of between 10-13 mm, the second section bifurcating upward into two branches one of which is longer than the other, extends along the warped axis, and is of substantially circular and uniform cross-sectional shape, the other branch being formed with a short laterally projecting extension of circular cross-sectional shape with a diameter between 10-13 mm, the branches forming with the conduit of a distorted "Y", the conduit being between 60-75 mm long overall, the one branch being between 18-25 mm long, and the other branch being between 4-8 mm long, the short branch having a wall that intercepts between 50%-70% of blood flowing up through the tubular conduit from the vena cava.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DAVID J. ISABELLA whose telephone number is 571-272-4749. The examiner can normally be reached on MONDAY-FRIDAY.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, CORRINE MCDERMOTT can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



DAVID J. SABELLA  
Primary Examiner  
Art Unit 3738

DJI  
7/27/2007